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Question 11: What roles should various sectors (e.g. industry, academia, government, foundations) play in the design, funding, oversight, reporting, and modification of post-marketing surveillance of newly introduced reduced risk products?

The goal of the post marketing surveillance studies is to assure that the newly introduced reduced risk products do indeed possess a reduced risk profile when used as intended by the public. These studies will be difficult to perform, most likely lasting decades. It is imperative that the studies be well designed and controlled and that the test hypothesis is agreed to by the relevant stakeholders prior to the start of the work. A system should be set up to:

- Review of the study design.
- Provide for interim analysis of the data.
- Provide for final review and publication of data.

All stakeholders should be invited to participate in the process. Table 1 shows the relationships and roles of the stakeholders in the generation and evaluation of data. The funding and execution of the studies should principally be provided by the manufacturer of the product. Other funding approaches should be encouraged to fully elucidate any potential benefits of the products.

The studies should be designed to evaluate the known risks of smoking as well as to detect any previously unknown effects. The studies should include evaluation of concomitant diseases as well as other risk factors such as diet and life style. A key aspect of the studies should be an evaluation of the effect of reduced risk product on smoking behavior. This should include the individual consumer's smoking behavior (~~i.e.,~~ changing how the consumer uses the product, for example, number of cigarettes per day or as an intermittent alternative to the "normal" product, or how the consumer physically smokes the product (size of puff, depth of inhalation, duration

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of puff hold.)) The study should also investigate the effect of the presence of the reduced risk product on the smoking population (i.e., does the new product encourage people to smoke that would normally not start or encourage people not to quit that might have quit if the new product were not available.)

A separate system should be set up to monitor the adverse events associated smoking as revealed by the medical community, independent research foundations, and consumers. One could envision a system similar to the Drug Experience Reports where all suspected adverse events could be reported and reviewed. Provisions should be made for consumers to be able to self-report events.

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Table 1: Role of Stakeholders in Post-Market Surveillance Research

Stakeholder	Post Market Surveillance Studies	Adverse Event Reporting	Epidemiology	Sales Data	Use Data	Mortality and Morbidity Data	Medical Literature
Tobacco Company	Lead	Contribute	Contribute	Lead	Contribute	Contribute	Contribute
Consumers		Contribute					
Research Foundations	Contribute	Contribute	Contribute		Contribute	Contribute	Contribute
Medical Community	Contribute	Contribute	Contribute		Contribute	Contribute	Lead
Federal Agencies	Contribute	Lead	Contribute		Contribute	Lead	
Foreign Regulatory Agencies	Contribute	Lead	Contribute		Contribute	Lead	
World Health Organization (IARC)	Contribute	Contribute	Contribute		Contribute	Lead	Contribute

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